

(g) *Compliance procedures.* A quality standard for bottled drinking water is established in §165.110(b) of this chapter. To assure that the plant's production of bottled drinking water complies with the applicable standards, laws, and regulations of the government agency or agencies having jurisdiction, the plant will analyze product samples as follows:

(1) For bacteriological purposes, take and analyze at least once a week for total coliform a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The representative sample shall consist of primary containers of product or unit packages of product. If any coliform organisms are detected, follow-up testing must be conducted to determine whether any of the coliform organisms are *E. coli*.

(2) For chemical, physical, and radiological purposes, take and analyze at least annually a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The representative sample(s) consists of primary containers of product of unit packages of product.

(3) Analyze such samples by methods approved by the government agency or agencies having jurisdiction. The plant shall maintain records of date of sampling, type of product sampled, production code, and results of the analysis.

(h) *Record retention.* All records required by §§129.1, 129.20, 129.35, 129.37, 129.40, and 129.80 shall be maintained at the plant for not less than 2 years. Plants shall also retain, on file at the plant, current certificates or notifications of approval issued by the government agency or agencies approving the plant's source and supply of product water and operations water. All required documents shall be available for official review at reasonable times.

[42 FR 14355, Mar. 15, 1977, as amended at 44 FR 12175, Mar. 6, 1979; 60 FR 57124, Nov. 13, 1995; 74 FR 25665, May 29, 2009]

## PART 130—FOOD STANDARDS: GENERAL

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AUTHORITY: 21 U.S.C. 321, 336, 341, 343, 371.

### Subpart A—General Provisions

#### § 130.3 Definitions and interpretations.

(a) The definitions and interpretations of terms contained in section 201 of the act shall be applicable also to such terms when used in regulations promulgated under the act.

(b) If a regulation prescribing a definition and standard of identity for a food has been promulgated under section 401 of the act and the name therein specified for the food is used in any other regulation under section 401 or any other provision of the act, such name means the food which conforms to such definition and standard, except as otherwise specifically provided in such other regulation.

(c) No provision of any regulation prescribing a definition and standard of identity or standard of quality or fill of container under section 401 of the act shall be construed as in any way affecting the concurrent applicability of the general provisions of the act and the

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regulations thereunder relating to adulteration and misbranding. For example, all regulations under section 401 contemplate that the food and all articles used as components or ingredients thereof shall not be poisonous or deleterious and shall be clean, sound, and fit for food. A provision in such regulations for the use of coloring or flavoring does not authorize such use under circumstances or in a manner whereby damage or inferiority is concealed or whereby the food is made to appear better or of greater value than it is.

(d) *Safe and suitable* means that the ingredient:

(1) Performs an appropriate function in the food in which it is used.

(2) Is used at a level no higher than necessary to achieve its intended purpose in that food.

(3) Is not a food additive or color additive as defined in section 201 (s) or (t) of the Federal Food, Drug, and Cosmetic Act as used in that food, or is a food additive or color additive as so defined and is used in conformity with regulations established pursuant to section 409 or 721 of the act.

(e) Section 403(i) of the act requires the listing of all ingredients in standardized foods. All ingredients must be listed in accordance with the requirements of part 101 of this chapter, except that where a definition and standard of identity has specific labeling provisions for optional ingredients, optional ingredients may be declared in accordance with those provisions.

[42 FR 14357, Mar. 15, 1977, as amended at 58 FR 2876, Jan. 6, 1993]

### § 130.5 Procedure for establishing a food standard.

(a) The procedure for establishing a food standard under section 401 of the act shall be governed by part 10 of this chapter.

(b) Any petition for a food standard shall show that the proposal, if adopted, would promote honesty and fair dealing in the interest of consumers.

(c) Any petition for a food standard shall assert that the petitioner commits himself to substantiate the information in the petition by evidence in a public hearing, if such a hearing becomes necessary.

(d) If a petitioner fails to appear, or to substantiate the information in his petition, at a public hearing on the matter, the Commissioner may either (1) withdraw the regulation and terminate the proceeding or (2) if he concludes that it is in accordance with the requirements of section 401 of the act, continue the proceeding and introduce evidence to substantiate such information.

[42 FR 14357, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977]

### § 130.6 Review of Codex Alimentarius food standards.

(a) All food standards adopted by the Codex Alimentarius Commission will be reviewed by the Food and Drug Administration and will be accepted without change, accepted with change, or not accepted.

(b) Review of Codex standards will be accomplished in one of the following three ways:

(1) Any interested person may petition the Commissioner to adopt a Codex standard, with or without change, by proposing a new standard or an appropriate amendment of an existing standard, pursuant to section 401 of the act. Any such petition shall specify any deviations from the Codex standard, and the reasons for any such deviations. The Commissioner shall publish such a petition in the FEDERAL REGISTER as a proposal, with an opportunity for comment, if reasonable grounds are provided in the petition. Any published proposal shall state any deviations from the Codex standard and the stated reasons therefor.

(2) The Commissioner may on his own initiative propose by publication in the FEDERAL REGISTER the adoption of a Codex standard, with or without change, through a new standard or an appropriate amendment to an existing standard, pursuant to section 401 of the act. Any such proposal shall specify any deviations from the Codex standard, and the reasons for any such deviations.

(3) Any Codex standard not handled under paragraph (b) (1) or (2) of this section may be published in the FEDERAL REGISTER for review and informal comment. Interested persons shall be